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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/559,661

02/01/2006

Mikio Aoki

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EXAMINER

BOWMAN, AMY HUDSON

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

11/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/559,661

Applicant(s)

AOKI, MIKIO

Examiner

Amy H. Bowman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-102 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-102 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-21 and 49, drawn to a method of nucleic acid infusion with the specific compounds recited in claims 7-21. **Election of this group requires further election of a single stranded or double stranded compound as recited in claim 4; a specific backbone and/or sugar modification from claim 5; and oligosaccharide or polyhydric alcohol species from claim 6.**

Furthermore, if oligosaccharide is elected from claim 6, applicant is required to elect a disaccharide from claim 8.

If polyhydric alcohol is elected from claim 6, applicant is required to elect a species from claim 9. If applicant elects polyol from claim 9, applicant is further required to elect a species from claim 19. If applicant elects sugar alcohol from claim 9, applicant is required to elect a species from claim 13. If applicant elects monosaccharide alcohol from claim 13, applicant is required to elect a species from claim 20. If applicant elects oligosaccharide alcohol from claim 13, applicant is required to elect a species from claim 21.

The species elections are further explained below.

It is noted that siRNA as recited in claim 5 will only be examined if double stranded compounds are elected from claim 4.

It is noted that antisense as recited in claim 5 will only be examined if single stranded compounds are elected from claim 4.

Group II, claims 1-6, 22-36 and 49, drawn to a method of nucleic acid infusion with the specific compounds recited in claims 22-36. **Election of this group requires further election of a single stranded or double stranded compound as recited in claim 4; a specific backbone and/or sugar modification from claim 5; and oligosaccharide or polyhydric alcohol species from claim 6.**

This group is based on the specific combination of compounds recited in instant claims 22-36. Applicant is required to elect oligosaccharide or sugar alcohol from claim 22, as well as diol, triol, or polyol from claim 22. The election must be commensurate with claim 6, from which it depends.

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Furthermore, if oligosaccharide is elected from claim 22, applicant is required to elect a disaccharide from claim 24.

If sugar alcohol is elected from claim 22, applicant is required to elect a species from claim 25. If applicant elects monosaccharide alcohol from claim 25, applicant is further required to elect a species from claim 27. If applicant elects oligosaccharide alcohol from claim 25, applicant is required to elect a species from claim 28.

If applicant elects polyol from claim 22, applicant is further required to elect a species from claim 36.

The species elections are further explained below.

It is noted that siRNA as recited in claim 5 will only be examined if double stranded compounds are elected from claim 4.

It is noted that antisense as recited in claim 5 will only be examined if single stranded compounds are elected from claim 4.

Group III, claims 1-6, 22, 37, 38 and 49, drawn to a method of nucleic acid infusion with the specific compounds recited in claims 22, 37 and 38. **Election of this group requires further election of a single stranded or double stranded compound as recited in claim 4; a specific backbone and/or sugar modification from claim 5; and oligosaccharide or polyhydric alcohol species from claim 6.**

This group is based on the specific combination of compounds recited in instant claims 22, 37 and 38. Applicant is required to elect oligosaccharide or sugar alcohol from claim 22, as well as diol, triol, or polyol from claim 22. The election must be commensurate with claim 6, from which it depends.

Applicant is required to elect one substance from part (1) of claims 37 and 38, as well as one substance from part (2) of claims 37 and 38, wherein the election is consistent with election of specific species from claim 22.

The species elections are further explained below.

It is noted that siRNA as recited in claim 5 will only be examined if double stranded compounds are elected from claim 4.

It is noted that antisense as recited in claim 5 will only be examined if single stranded compounds are elected from claim 4.

Group IV, claims 1-6, 39-45 and 49, drawn to a method of nucleic acid infusion with the specific compounds recited in claims 39-45. **Election of this group requires further election of a single stranded or double stranded compound as recited in claim 4; a specific backbone and/or sugar modification from claim 5; and oligosaccharide or polyhydric alcohol species from claim 6.**

This group is based on the specific combination of compounds recited in instant claims 39-45. Applicant is required to elect oligosaccharide or sugar alcohol from

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claim 39. The election must be commensurate with claim 6, from which it depends.

Furthermore, if oligosaccharide is elected from claim 39, applicant is required to elect a disaccharide from claim 41.

If sugar alcohol is elected from claim 39, applicant is required to elect a species from claim 42. If applicant elects monosaccharide alcohol from claim 42, applicant is further required to elect a species from claim 44. If applicant elects oligosaccharide alcohol from claim 42, applicant is required to elect a species from claim 45.

The species elections are further explained below.

It is noted that siRNA as recited in claim 5 will only be examined if double stranded compounds are elected from claim 4.

It is noted that antisense as recited in claim 5 will only be examined if single stranded compounds are elected from claim 4.

Group V, claims 1-6, 39, 46 and 49, drawn to a method of nucleic acid infusion with the specific compounds recited in claims 39 and 46. **Election of this group requires further election of a single stranded or double stranded compound as recited in claim 4; a specific backbone and/or sugar modification from claim 5; and oligosaccharide or polyhydric alcohol species from claim 6.**

This group is based on the specific combination of compounds recited in instant claims 39 and 46. Applicant is required to elect oligosaccharide or sugar alcohol from claim 39. The election must be commensurate with claim 6, from which it depends.

Furthermore, applicant is required to elect sucrose, mannitol, sorbitol, xylitol or maltitol from claim 46 for examination.

The species elections are further explained below.

It is noted that siRNA as recited in claim 5 will only be examined if double stranded compounds are elected from claim 4.

It is noted that antisense as recited in claim 5 will only be examined if single stranded compounds are elected from claim 4.

Group VI, claims 50-66, 92-96 and 98, drawn to a reagent for nucleic acid infusion.

Election of this group requires further election of oligosaccharide or polyhydric alcohol from claim 50. Upon election of oligosaccharide, applicant is required to elect one species from claim 53. Upon election of polyhydric alcohol, applicant is required to elect a species from claim 54.

Upon election of polyol from claim 54, applicant is required to elect a species from claim 64. Upon election of sugar alcohol from claim 54, applicant is required

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to elect a species from claim 58. Upon election of monosaccharide alcohol from claim 58, applicant is required to elect a species from claim 65. Upon election of oligosaccharide alcohol from claim 58, applicant is required to elect a species from claim 66.

Furthermore, applicant is required to elect one specific combination of oligosaccharide or polyhydric alcohol from claim 93, which is consistent with the elections of the rest of the claims of the group.

The species elections are further explained below.

Group VII, claims 50, 51, 67-81, 92-96 and 98, drawn to a reagent for nucleic acid infusion. Election of this group requires further election of oligosaccharide or polyhydric alcohol from claim 50. Applicant is required to elect one substance from part (1) of claim 67, as well as one substance from part (2) of claim 67, which are consistent with the species election of claim 50.

Upon election of oligosaccharide from claim 67, applicant is required to elect one species from claim 69. Upon election of sugar alcohol from claim 67, applicant is required to elect a species from claim 70. Upon election of monosaccharide alcohol from claim 70, applicant is required to elect a species from claim 72. Upon election of oligosaccharide alcohol from claim 70, applicant is required to elect a species from claim 73.

Upon election of polyol from claim 67, applicant is required to elect a species from claim 81.

Furthermore, applicant is required to elect one specific combination of oligosaccharide or polyhydric alcohol from claim 93, which is consistent with the elections of the rest of the claims of the group.

The species elections are further explained below.

Group VIII, claims 50, 51, 67, 82, 92-96 and 98, drawn to a reagent for nucleic acid infusion. Election of this group requires further election of oligosaccharide or polyhydric alcohol from claim 50. Applicant is required to elect one substance from part (1) of claim 67, as well as one substance from part (2) of claim 67, which are consistent with the species election of claim 50.

Furthermore, applicant is required to elect one substance from part (1) of claim 82, as well as one substance from part (2) of claim 82, the elections of which must be consistent with the species elections of claims 50 and 67.

Furthermore, applicant is required to elect one specific combination of oligosaccharide or polyhydric alcohol from claim 93, which is consistent with the elections of the rest of the claims of the group.

The species elections are further explained below.

Group IX, claims 50, 51, 67, 82, 83, 92-96 and 98, drawn to a reagent for nucleic acid infusion. Election of this group requires further election of oligosaccharide or

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polyhydric alcohol from claim 50. Applicant is required to elect one substance from part (1) of claim 67, as well as one substance from part (2) of claim 67, which are consistent with the species election of claim 50.

Furthermore, applicant is required to elect one substance from part (1) of claim 82, as well as one substance from part (2) of claim 82, the elections of which must be consistent with the species elections of claims 50 and 67.

Furthermore, applicant is required to elect one substance from part (1) of claim 83, as well as one substance from part (2) of claim 83, the elections of which must be consistent with the species elections of claims 50, 67 and 82.

Furthermore, applicant is required to elect one specific combination of oligosaccharide or polyhydric alcohol from claim 93, which is consistent with the elections of the rest of the claims of the group.

The species elections are further explained below.

Group X, claims 50, 51, 84-90, 92-96 and 98, drawn to a reagent for nucleic acid infusion. Election of this group requires further election of oligosaccharide or polyhydric alcohol from claim 50. Applicant is required to elect oligosaccharide or sugar alcohol from claim 84. Upon election of oligosaccharide, applicant is required to elect a species from claim 86. Upon election of sugar alcohol from claim 84, applicant is required to elect a species from claim 87. Upon election of monosaccharide alcohol from claim 87, applicant is required to elect a species from claim 89. Upon election of oligosaccharide alcohol from claim 87, applicant is required to elect a species from claim 90.

Furthermore, applicant is required to elect one specific combination of oligosaccharide or polyhydric alcohol from claim 93, which is consistent with the elections of the rest of the claims of the group.

The species elections are further explained below.

Group XI, claims 50, 51, 84, 91-96 and 98, drawn to a reagent for nucleic acid infusion. Election of this group requires further election of oligosaccharide or polyhydric alcohol from claim 50. Applicant is required to elect oligosaccharide or sugar alcohol from claim 84. Applicant is required to elect one species from claim 91 that is consistent with the species elections from claims 50 and 84.

Furthermore, applicant is required to elect one specific combination of oligosaccharide or polyhydric alcohol from claim 93, which is consistent with the elections of the rest of the claims of the group.

The species elections are further explained below.

Group XII, claim 97, drawn to the use of a reagent or kit according to claim 50.

Election of this group requires further election of oligosaccharide or polyhydric alcohol from claim 50. The species election is further explained below.

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Group XIII, claim 99-101, drawn to a cell with a nucleic acid infused therein by a method of claim 1, as well as cell derived RNA or protein prepared from a cell according to claim 99. **Election of this group requires further election of one cell type from claim 100. The species election is further explained below.**

Group XIV, claim 102, drawn to a method of functional analysis of a gene or protein associated with an infused nucleic acid.

It is noted that claims 47 and 48 have not been grouped because they recite oligosaccharide and polyhydric alcohol of claim 1, although claim 1 does not recite these compounds.

The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

37 CFR 1.475(b) states:

"An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn **only** to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475(d) also states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)."

37 CFR 1.475(e) further states:

"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim."

In the instant case, the product is not the first claimed invention and therefore there is no unity of invention between the product and processes. Furthermore, the instant claims do not all fall into one of the only 5 combinations of categories which can have unity of invention as defined by 1.475(b), as the claims are directed to a multitude of methods and compounds.

Additionally, the technical feature of claim 1 is a method of nucleic acid infusion comprising steps (a) and (b), which is not novel in view of the International Search Report filed on 12/5/05 (see X reference of Gopal et al. (Mol. Cell Biol., Vol. 5, No. 5, pages 1188-1190, 1985). Therefore, there is no special technical feature linking the groups listed above.

Additionally, claims 4 and 5 are directed to single and double stranded oligonucleotides. According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature. For chemical alternatives, such as the claimed structures, the Markush group shall be regarded as being of similar nature when

- (A) all alternatives have a common property or activity and; (B)(1) a common structure is present, i.e., a significant structure is shared by all of the alternatives; or (B)(2) in cases where the common structure cannot be

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the unifying criteria, all alternatives belong to an art-recognized class of compounds in the art to which the invention pertains.

The instant structures are considered to be each separate inventions for the following reasons: The structures do not meet the criteria of (A), common property or activity or (B)(2), art recognized class of compounds. The structures each behave in a different way in the context of the claimed invention, as single stranded and double stranded oligonucleotides do not act via the same mechanism within the context of the instant inventions. Each member of the class cannot be substituted, one for the other, with the expectation that the same intended result would be achieved. Further, the structures do not meet the criteria of (B)(1), as they do not share, one with another, a common core structure. Accordingly, unity of invention between single and double stranded compounds is lacking and each structure is considered to constitute a special technical feature. Accordingly, upon election of group I, applicant is further required to elect single or double stranded oligonucleotides for examination within the instant method. The oligonucleotides of claim 5 will be examined to the extent to which they read on the elected single or double stranded oligonucleotides.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The instant claims recite a multitude of species of substances, as described in the specific groupings of claims above. Each of the specific substances are structurally

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distinct, containing no common structural core. To search for any one of the specific substances or combinations of substances would not necessarily return art against any of the other substances or combinations of substances. Therefore, upon election of a group, applicant is required to elect specific species of substances as explained in each of the claim groupings above. The claims will be examined to the extent to which they read on the specific species that is elected.

Furthermore, claim 5 recites several species of specific modifications. Each of the modifications (phosphorothioate, 2'-O-(2-methoxy)ethyl, LNA, PNA or morpholino) are separate and distinct structures, each requiring a separate and distinct search and corresponding examination.

Furthermore, claim 100 recites multiple species of cells. Each of the cell types are structurally and functionally distinct, each requiring a separate and distinct search and corresponding examination.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is (571) 272-0755. The examiner can normally be reached on Monday-Thursday 6:30 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amy H. Bowman/
Patent Examiner
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